

REMARKS

As stated in the Preliminary Amendment of September 23, 2002, claims 1-4, 6-14, and 19-24 are pending in the application. Applicant offers the following remarks, along with a Declaration Under 37 CFR §1.132 by the inventor Dr. Pawan Seth for consideration by the Examiner.

Clarification of Claim 3

In the Preliminary Amendment of September 23, the clean version of claim 3 (twice amended) was incorrectly given. Attention is respectfully drawn to the marked-up version of claim 3 in the Preliminary Amendment, which is correct. For clarification, a clean version of claim 3 is given below. The clean version below differs from the clean version offered on September 23 by the inclusion of the words "selected from the" between the words "plasticizer" and "group" in line 3.

3. (Twice Amended) A composition according to claim 1, wherein the coating further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

Declaration of Dr. Seth

In the Preliminary Amendment, Applicant argued that the differences between the current claims and the disclosure of the Morella references are such that it would not have been obvious to one of skill in the art to modify the disclosure of the Morella reference to arrive at the claims. Applicant pointed out that the differences between the Morella reference and the current claims were at least the following:

1. The current claims recite that the coating comprises from 30 to 80% of a gastroresistant resistant polymer soluble at a pH above 5.5. Applicant demonstrated in the Preliminary Amendment that the Morella reference, on the other hand, teaches an analogous component at a level of 1-30%, preferably 2-20%.

2. The current claims (the independent claims 1, 9, and 11) recite the presence of a hydrophilic silicon dioxide in the coating. The Morella reference does not disclose or suggest the use of hydrophilic silicon dioxide.

3. The Morella reference requires the presence of an insoluble matrix polymer in its coating. Such a limitation is missing from the current claims.

Significantly, the current claims state the gastroresistant polymer is soluble at a pH of 5.5 or greater. Furthermore, claims 22-24 recite that the entire coating itself is soluble at a pH at 5.5 or above. Such is not the case for the coating of the Morella reference, since it comprises an insoluble polymer.

For a discussion of the solubility of the coatings, attention is respectfully drawn to the enclosed Declaration Under 37 C.F.R. §1.132 of Dr. Pawan Seth. Dr. Seth prepares a core containing Verapamil and two different coatings for comparison. The first is a coating according to the current claims; the second is according to formulation 3 of column 14 of the Morella patent. (See Section 5). Annex 1 shows that the dissolution profiles of the two coatings are similar at pH 1.2 (the pH of the stomach). Annex 2 shows that the dissolution profile of the Morella composition is quite different from that of the current invention at a pH above 5.5 (the pH of the intestine).

At paragraph 11, Dr. Seth discusses the food effect as it applies to the compositions of Morella. Since the drug released in the body is only about 20% after 18 hours (Annex 2), the Morella formulation actually does not avoid the food effect. Rather the difference in the fed and non fed conditions cannot be detected. For example, if there were a 30% food effect, then 30% of the 20% absorbed after 18 hours would be 6%, a total that cannot be detected. As explained at paragraph 10, the Morella formulation simply slows the release of the drug throughout the gastrointestinal tract. The Morella formulation shows no difference in the release of the drug in the stomach and the intestine.

In other words, while the Morella reference teaches that there is no food effect, this is due to the very slow release of the active ingredient in Morella that makes food effect of no importance. In contrast, the invention recited in the current claims provides release in the intestine (selectively) so that food effect is avoided and the effective amount of drug absorbed is greater.

On the basis of the discussion above, Applicant respectfully submits that in light of differences between the Morella reference and the current claims, it would not have been obvious to modify the disclosure of the Morella reference to arrive at the current claims. For this reason, and for the reasons discussed in the Preliminary Amendment of September 23, Applicant believes that the claims as currently amended are patentable over the cited Morella Reference.

CONCLUSION

For the above reasons, Applicant believes that claims 1-4, 6-14 and 19-24 are in an allowable condition and respectfully request an early notice of such allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issue.

Respectfully submitted,

Dated:

Oct. 24, 2002

By:

Mark A. Frentrop

Monte L. Falcoff, Reg. No. 37,617

Mark A. Frentrop, Reg. No. 41,026

Attorneys for Applicant

HARNES, DICKY & PIERCE, P.L.C.
P.O. Box 828
Bloomfield Hills, Michigan 48303
(248) 641-1600